UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/233,218	01/20/99	CAJACOB	C 04983.0025.U

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HM12/0716

EXAMINER	
KIM, Y	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/233,218	CAJACOB ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1,2 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 10-21* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This Office Action responds the Amendment received on April 23, 2001 (Paper No. 16).

Preliminary Remark

The Office acknowledges the cancellation of claims 3-9, drawn to non-elected invention and the addition of claims 11-21, drawn to the elected invention.

Claim Rejections - 35 USC § 101

The rejection of claims 1-2, and 10 under 35 U.S.C. 101 for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility in the Office Action mailed on February 1, 2001 is withdrawn in view of careful reconsideration and the Amendment received on April 23, 2001.

Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-21 are rejected under 35 U.S.C. 101 for lacking patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Applicants' argument have been fully considered but they are not found persuasive.

Applicants argue that the Office has not established a *prima facie* standard in rejecting the claims because the rejection was based on "allegations, without support" (2nd paragraph, pp. 5). Applicants further state that substantial utilities for the claimed nucleic acids of the invention

have been asserted and absent evidence to the contrary, such assertion must be accepted (3rd paragraph, pp. 5). Applicants then recites a list of possible utilities that are applicable to any nucleic acids in general, that is , detecting mutations, determining expression levels, etc.

As already set forth in the Office Action mailed on February 1, 2001, the claimed nucleic acids lack a patentable utility because Applicants haven't demonstrated that the claimed nucleic acids indeed exhibited the asserted utility of glutamyl tRNA reductase enzyme. The only evidence to which Applicants are relying upon is the percent similarity of the sequence of the claimed nucleic acid and the sequence of glutamyl tRNA reductase. It appears that Applicants desire evidence for the Office's determination of lack of utility based on homology. Such evidence will follow the present Office Action [See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981{1996)]; Wells et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)]].

Based on the above reasoning, the claimed nucleic acid lack specific utility because the nucleic acids are not disclosed as being useful as probes for detecting a specific condition, primers for amplifying a target region which would serve as an indication of some condition, etc. Simply stating that a nucleic acid could be used as a probe, primer, or anything for that matter, would be equivalent to saying that a single piece of nucleotide could be patented because a string of nucleotides could be used as a probe or a primer. The claimed nucleic acids must demonstrate real world applications that are specific, (i.e., markers, probes, for detection of a

specific condition). The nucleic acids of the instant application lack such utility and thus, the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 11-21 under 35 U.S.C. 112, first paragraph because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above in the Office Action mailed on February 1, 2001 is maintained for the reasons of record. Applicants' argument received on April 23, 2001 has been addressed above.

New Grounds (Necessitated by Amendment) Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction

or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

A) The specification discloses nucleic acids of SEQ ID Numbers that exhibit some percent similarity to that of the sequence of glutamyl tRNA reductase. However, the specification does not give any evidence that the nucleic acids of the instant application has the same function as that of glutamyl tRNA reductase. Applicants rely on the homology of the nucleic acids of the instant application to that of glutamyl tRNA reductase for its function. Absent evidence to the contrary, it would require undue experimentation of a skilled artisan to use the claimed nucleic acid for its use as glutamyl tRNA reductase without undue experimentation because the prior art nor the specification teach the disclosed sequences as being useful as glutamyl tRNA reductase.

B) Amount of direction/guidance: The specification does not give any direction or guidance in using the disclosed nucleic acid sequences as glutamyl tRNA reductase.

C) Absence of Working Example: The specification does not give any example in demonstrating that the nucleic acids have the same function as glutamyl tRNA reductase.

D) Nature of Invention: The nature of the invention relates to nucleic acids derived from a sample and its correlation of function based on homology.

E) Prior art: There are no prior art teachings that show the nucleic acids of the instant application having glutamyl tRNA reductase function.

F) Skill Level: The skill level of the artisan is considered to be high.

G) Unpredictability of the art: It is noted that applicant(s) have listed a sequence which has a high percentage sequence similarity to a known sequence. Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981{1996)]; Wells et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)].

H) Breadth of Claims: The breadth of claims encompasses a nucleic acid molecule that does not exhibit the same function as glutamyl t-RNA reductase enzyme.

As set forth above, it would require undue experimentation of a skilled artisan to practice the invention as claimed because the skilled artisan would not be able to find teachings or

guidance demonstrating that the disclosed nucleic acid sequences have the same function as glutamyl t-RNA reductase enzyme.

The rejection of claims 1, 2, and 10 (and newly submitted claims 11-21) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention in the Office Action mailed on February 1, 2000 is maintained for the reasons of record.

Applicants' arguments received on April 23, 2001 have been fully considered but they are not found persuasive.

Applicants argue that and adequate written description of a genus of nucleic acids, as recited in claims 1 and 10, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequences, falling within the scope of the genus or of a recitation of structural features common to the members of the genus (pp. 7). Thus, Applicants argue that the claimed SEQ ID Numbers are members of the claimed genera of claims 1 and 10, sharing common features with all the members of the claimed group.

Examiner respectfully disagrees. The written description rejection was based on the fact that the specification lacked evidence disclosing a complete open reading frame comprising the nucleic acids being claimed. Without such disclosure, a nucleic acid comprising the claimed fragments of nucleic acids would necessarily read on genes and allelic variants that are not described at the time the inventors filed the application.

Applicants are advised to point to the specification where such complete open reading frames for each of the claimed nucleic acid fragments are disclosed.

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. Papers related to this application may be submitted to Art Unit 1631by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

07/10/01

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER